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**REMARKS**

Claims 1 through 6 and new Claim 7 are pending in the application.

Claim 1 has been amended to emphasize that the inventive methods for removing contaminating or undesired substances (hereinafter "contaminants") are directed to carrier materials which have been coated with an active ingredient containing coating which forms an active ingredient containing film, the resulting active ingredient containing film has been peeled off the carrier material and the carrier material has been contaminated by contaminants stemming from the coating. Support for this amendment can be found in the Application-as-filed, for example in Claim 4.

Claim 1 has further been amended to reflect that the inventive methods for removing contaminants advantageously include the steps of allowing the contaminated carrier to pass through a thermal treatment zone at a temperature and for a period of time sufficient to remove essentially all of the contaminants from the carrier material. Support for this amendment can be found in the Application-as-filed, for example in Claim 2.

Claim 1 has additionally been amended to reflect that inventive methods advantageously include feeding the removed contaminants to a thermal after-burning using a controlled air circulation. Support for this amendment can be found in the Application-as-filed, for example on Page 5, lines 12 through 14.

Claim 2 has been amended to reflect advantageous methods in which the thermal treatment is performed at a temperature of approximately 80 °C and the treatment duration is approximately 0.5 to 6 minutes. Support for this amendment can be found in the Application-as-filed, for example on Page 5, lines 4 through 6.

Claim 4 has been canceled, as its subject matter has been incorporated into Claim 1.

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Claims 5 and 6 have been amended to conform to Claim 1 as-amended.

Claim 7 has been added to complete the record for examination and highlight advantageous embodiments of the invention. Claim 7 is directed to advantageous methods that further include (i) optionally cooling the treated carrier, and (ii) coating the treated and optionally cooled carrier. Support for this amendment can be found in the Application-as-filed, for example on Page 5, lines 8 through 16.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

*The Claimed Invention is Patentable  
in Light of the Art of Record*

Claims 1 through 3 stand rejected as anticipated by United States Patent No. 4,871,559 ("US 559") to Dunn et al.

Claims 1 and 4 through 6 stand rejected as being unpatentable over United States Patent No. 4,517,173 ("US 173") to Kizawa et al. in light of the Cookware Care section of the DuPont Teflon® website ("DuPont webpage").

It may be useful to briefly consider the invention before addressing the merits of the rejection.

Drugs, confectionary and the like (hereinafter referred to as "consumables") are known for consumption in sheet-like, wafer-like or film-like forms (hereinafter referred to as "film-form"). Various production processes are known for the manufacture of film-form consumables.

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In general, film-form consumables are manufactured on fully automated production lines by forming thin sheets of an active-ingredient film on a carrier material. The active-ingredient containing film is then typically peeled off of the carrier material and the separated active-ingredient containing film cut into suitably sized and shaped pieces for administration. The separated carrier material is taken up onto a reel.

Unfortunately, during the film-form production process the active-ingredient (as well as any additional adjuvants or other coating compounds) can penetrate into the carrier material due to diffusion. The carrier material is then contaminated by these substances, up to their respective degree of saturation. Consequently, once the active ingredient containing film has been peeled off the carrier material, the contaminated carrier material can not be used again, since it is loaded to a non-specified degree with diffused active ingredients and the like (hereinafter referred to as "contaminants," as noted above). If the carrier were to be coated a second time, the active ingredients, etc. would penetrate to a different extent, due to the contaminants already present within the carrier. Thus the composition of the resulting active ingredient containing film could change significantly. This is especially unacceptable for the film-form administration of drugs, making any further use of the carrier material almost impossible.

The present invention provides a method for the removal of carrier material contaminants, resulting in a "neutralized" carrier material that is essentially contaminant-free and which can be used again, for example in the production of further film-form consumables.

Altogether unexpectedly, contaminants can be evaporated from carrier materials using simple thermal treatments performed at moderate temperatures and durations, and the evaporated contaminants can then be permanently disposed of by feeding the evaporated contaminants to a thermal after-burner using controlled air circulation, as recited in the claims as-amended.

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In particularly advantageous embodiments, the thermal treatment is performed at a temperature of approximately 80 °C for a period of approximately 0.5 to 6 minutes, as recited in Claim 2 as-amended.

In especially advantageous embodiments, the inventive carrier material decontamination allows the neutralized carrier to be used again as a carrier in subsequent coatings. In such advantageous processes, the inventive methods further include (i) optionally cooling the treated carrier and (ii) coating the treated and optionally cooled carrier, as recited in new Claim 7.

The claimed methods thus provide the added advantage of easy integration into manufacturing processes, especially the manufacturing processes used to produce film-form consumables.

The cited references do not teach or suggest the invention recited in the claims as-amended.

US 559 is generally directed to methods to reduce or eliminate chemical preservatives in foods and/or packaging. (Col. 1, lines 26 – 31). US 559 is more particularly directed to a method for food preservation and packaging incorporating microbial and/or enzymatic deactivation processes based on intense, short pulses of incoherent, broad spectrum light. (Col. 4, lines 3 – 9). ). The incoherent light pulses are provided by a flashlamp system. (Col. 11, lines 16 – 18). The short pulses range in duration from  $1 \times 10^{-6}$  to about  $1 \times 10^{-1}$  seconds. (Col. 4, lines 18 – 33). US 559 indicates that “even at very high organism densities” only one or two flashes will result in sterilization of spores and vegetative bacteria and viruses. (Col. 16, lines 43 – 47).

US 559 indicates that any heat generated is localized at a very superficial surface layer, thereby killing surface microorganisms and inactivating surface enzymes, without significantly raising the interior temperatures of the food product. (Col. 7, lines 15 – 19). US 559 goes on to teach that, in contrast to conventional continuous light treatments, short pulses of incoherent light

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give rise to little or no thermal conduction. (Col. 8, lines 7 – 32). US 559 expressly discloses that “the product (except for a very superficial surface layer) is not heated to a temperature that would substantially alter its characteristics.” (Col. 10, lines 32 – 35) US 559 further notes that a “final wash” may be used. (Col. 12, lines 64 – 66).

Applicants respectfully submit that US 559 does not teach or suggest the claimed invention.

US 559, directed to the reducing chemical preservatives, does not teach or suggest methods for removing contaminants from carrier materials, much less carrier materials which have been contaminated by an active-ingredient-containing coating that formed an active-ingredient-containing film, as recited in the claims.

Nor does US 559, directed to pulsed light treatment and optional washing, teach or suggest the claimed methods of passing such contaminated carrier material through a thermal treatment zone at a temperature and time sufficient to remove essentially all of the contaminants from the carrier material. In fact, Applicants respectfully submit that to modify US 559 so as to incorporate such thermal treatment in lieu of its required incoherent light pulses would render it unfit for its intended purpose.

And US 559 most certainly does not teach or suggest feeding the removed contaminants to a thermal after-burning using a controlled air circulation, as further recited in the claimed invention.

US 559, teaching one or two short light pulses in a duration of as little as  $1 \times 10^{-6}$  seconds per flash, likewise fails to teach or suggest advantageous methods in which the thermal treatment is performed at a temperature of approximately 80 °C for a period of time of up to 6 minutes, as recited in Claim 2 as-amended.

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US 559, altogether silent as to recycling, can not teach or suggest the advantageous inventive methods further comprising optionally cooling the treated carrier and subsequently coating the treated (and optionally cooled) carrier, as recited in newly added Claim 7.

Applicants respectfully make of record that an important difference between US 559 and the present invention is that the present invention removes substances which penetrate the carrier material during the production process, resulting in the recited treated carrier material that is essentially contaminant-free. Applicants respectfully submit that the surface layer treatment of US 559 would not be sufficient for the removal of the substances in accordance with the present invention, because the treatment of US 559 is localized only at the surface layer. The difference in treatment depths between the present invention and US 559 is clearly evidenced by their respective methods. Highly beneficial results in the present invention are achieved by treating carrier materials at approximately 80 °C for a period of up to 6 minutes. In contrast, US 559 exposes surfaces to 1 or 2 flashes of incoherent light in a duration of as little as  $1 \times 10^{-6}$  seconds per flash. Accordingly, as acknowledged numerous times within US 559, its treatment depth is merely superficial.

Accordingly, Applicants respectfully submit that US 559 does not teach or suggest the claimed invention, considered either alone or in combination with the remaining art of record.

US 173 and the Du Pont webpage likewise fail to teach or suggest the claimed invention.

US 173 generically discloses a method for preparing a multi-layered film that includes a "poor water-soluble layer." (Col. 2, lines 14 – 21). The films of US 173 are formed by applying solutions on a base plate having a favorable releasing nature, for example, a Teflon<sup>®</sup> plate or a glass plate, and then removing the solvent. (Col. 4, lines 56 – 59). The films may be formed by setting a "frame mold" on the base plate and pouring various solutions into the frame mold. (Col. 4, lines 67 – 68). The film is stripped from the frame mold upon setting. (Col. 6,

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lines 5 - 6). US 173 is altogether silent as to the subsequent cleaning of the base plate; however, as correctly noted by the Examiner.

US 173 thus does not teach or suggest the recited removal of contaminants from a carrier material.

The DuPont webpage does not cure the deficiencies in US 173.

Evidencing conventional wisdom, the DuPont webpage discloses the cleaning of Teflon<sup>®</sup> surfaces by washing.<sup>1</sup> The webpage goes on to note that during washing, "a little more elbow grease" may be required for carbonized residues. Hence washing, i.e. an activity requiring at least some level of "elbow grease" for non-carbonized residues, constitutes a mechanical treatment (albeit a wet one), in contrast to the urgings of the outstanding Office Action.

There would have been no motivation to have combined the foregoing references. However even if combined (which Applicants most certainly did not) the claimed invention would not result.

US 173 is altogether silent as to the cleaning of its base plate. The DuPont webpage indicates that Teflon<sup>®</sup> is to be subjected to conventional washing.

Accordingly, the combination of US 173 and the DuPont webpage does not teach or suggest methods for removing contaminants from carrier materials that include passing such a carrier through a thermal treatment zone at a temperature and for a time sufficient to remove essentially all of the contaminants from the carrier material. In fact, Applicants respectfully

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<sup>1</sup> Applicants respectfully submit that although the cited information is open to the public, the specific date of initial publication was not disclosed. Therefore, Applicants respectfully submit that the DuPont webpage may not constitute prior art, and is thus not relevant. Out of an abundance of caution, Applicants nevertheless provide distinguishing remarks.

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submit that the DuPont webpage teaches away from the inventive processes by instead teaching that surfaces should be washed, which, as noted above, constitute a mechanical treatment.

And the combination of US 173 and the DuPont webpage most certainly does not teach or suggest feeding removed contaminants to a thermal after-burning using a controlled air circulation, as further recited in the claimed invention.

The combination of US 173 and the DuPont webpage, teaching the conventional washing of surfaces, likewise fails to teach or suggest advantageous methods in which the thermal treatment is performed at a temperature of approximately 80 °C for a period of time of up to 6 minutes, as recited in Claim 2 as-amended.

The combination of US 173 and the DuPont webpage, both of which are silent as to recycling, can not teach or suggest the advantageous inventive methods further comprising feeding the carrier to a thermal treatment zone in the form of a drying tunnel, optionally cooling the treated carrier, and coating the treated (and optionally cooled) carrier, as recited in newly added Claim 7.

Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of US 173 and the DuPont webpage, considered either alone or in combination.

Applicants further respectfully submit that US 500 similarly does not teach or suggest the claimed invention.

Claims 1 and 10 through 12 of US 500 are directed to coating methods that include transfer of a coating from a transfer support web to an intermediate support material. Claim 10 merely generically notes that the transfer support web can be regenerated. Claim 11 is directed to mechanical treatment and vacuum cleaning as regeneration methods. Claim 12 is directed to



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methods of Claim 11 that further include wet or chemical decontamination as a regeneration method.

In contrast to the mechanical and mechanical/chemical cleanings of US 500, the claimed invention removes contaminants penetrating the carrier material by thermal treatment alone.

And US 500 most certainly does not teach or suggest feeding removed contaminants to a thermal after-burning using a controlled air circulation, as further recited in the claimed invention.

US 500, teaching mechanical or mechanical/chemical decontamination, likewise fails to teach or suggest advantageous methods in which the thermal treatment is performed at a temperature of approximately 80 °C for a period of time of up to 6 minutes, as recited in Claim 2 as-amended.

US 500 likewise does not teach or suggest the advantageous inventive methods further comprising feeding the carrier to a thermal treatment zone in the form of a drying tunnel, optionally cooling the treated carrier, and coating the treated (and optionally cooled) carrier, as recited in newly added Claim 7.

Accordingly, Applicants respectfully submit that the claimed invention is also patentable in light of Claims 1 and 10 through 12 of US 500.

#### Confirmation of Receipt of Foreign Priority Documents

It is noted that the Examiner has not acknowledged receipt of the foreign priority document(s) for the present application. Accordingly, it is requested that the Examiner acknowledge receipt of the foreign priority document(s) in the next communication from the PTO. If priority documents have not been received, Applicant will be pleased to submit a request to WIPO, requesting that they forward the same in conformance with PCT practice.

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It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 3 and 5 through 7 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

*Cathy Moore*

Cathy R. Moore  
Reg. No. 45,764

ProPat, L.L.C.  
425-C South Sharon Amity Road  
Charlotte, NC 28211-2841  
Telephone: (704) 365-4881  
Fax: (704) 365-4851  
Customer No. 38263

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I hereby certify that this correspondence is being facsimile transmitted to the USPTO at facsimile no. (571) 273-8300 on April 11, 2008. Claire Wygand Claire Wygand